AUG 5 - 2005

# 510(k) SUMMARY

**GII Quickanchor Plus**

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| **Submitter's Name and Address:** | DePuy Mitek<br>a Johnson & Johnson company<br>249 Vanderbilt Avenue<br>Norwood, MA 02062 |
| **Contact Person** | Denise Luciano<br>Senior Regulatory Affairs Specialist<br>DePuy Mitek<br>a Johnson & Johnson company<br>249 Vanderbilt Avenue<br>Norwood, MA 02062<br>Telephone: 781-251-2794<br>Facsimile: 781-278-9578<br>e-mail: dluciano@dpyus.jnj.com |
| **Name of Medical Device** | Classification Name: Screw, Fixation, Bone Staple<br>Common/Usual Name: Appliance for reconstruction of soft tissue to bone<br>Proprietary Name: GII Quickanchor Plus |
| **Substantial Equivalence** | GII Quickanchor Plus (with ORTHOCORD) is substantially equivalent to:<br>GII Quickanchor Plus, K041115, manufactured by DePuy Mitek. |
| **Device Classification** | Bone anchors/screws are classified by the FDA as Class II Medical Devices under the generic category of Single/Multiple component metallic bone fixation appliances and accessories.<br><br>GII Quickanchor Plus carry FDA product code JDR, and is classified as a fixation screw/bone staple under 21 CFR 888.3030. |
| **Device Description** | GII Quickanchor Plus (with ORTHOCORD) is a preloaded, metallic disposable suture anchor/ inserter assembly designed to allow soft tissue repair to bone. The metal anchor is an identical anchor as that of the GII Quickanchor Plus in design, configuration and dimensions. The anchor system may be sold with Ethibond Suture (NDA 17-804 |

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| | and 17-809), Panacryl Suture (K964345), or Orthocord Suture (K040004 and K043298). |
| **Indications for Use** | The Mitek GII Anchor (QUICKANCHOR) is intended for fixation of USP size #2 suture to bone for the indications listed below.<br><br>Shoulder: Bankart repair, SLAP lesion repair, acromio-clavicular separation, rotator cuff repair, capsule shift/capsulo-labral reconstruction, biceps tenodesis, deltoid repair.<br><br>Ankle: Lateral instability, medial instability, achilles tendon repair/reconstruction, midfoot reconstruction.<br><br>Foot: Hallux valgus reconstruction.<br><br>Wrist: Scapholunate ligament.<br><br>Hand: Ulnar or lateral collateral ligament reconstruction.<br><br>Elbow: Tennis elbow repair, biceps tendon reattachment.<br><br>Knee: Extra capsular repairs; Reattachment of: medial collateral ligament, lateral collateral ligament, posterior oblique ligament or joint capsule to tibia and joint capsule closure to anterior proximal tibia; extra capsular reconstruction, ITB tenodesis; patellar ligament and tendon avulsions. |
| **Safety and Performance** | The determination of substantial equivalence for this device was based on a detailed device description, and conformance to consensus and voluntary standards. Bench testing was performed demonstrating that the ORTHOCORD suture conformed to the USP monograph for absorbable sutures, and the suture compatibility and deployment met predetermined acceptance criteria.<br><br>Based on the indications for use, technological characteristics, and comparison to predicate devices, the GII Quickanchor Plus has been shown to be substantially equivalent to predicate devices under the Federal Food, Drug and Cosmetic Act. |

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Ms. Denise Luciano
Senior Regulatory Affairs Specialist
DePuy Mitek
a Johnson & Johnson company
249 Vanderbilt Avenue
Norwood. Massachusetts 02062

Re: K051989
Trade/Device Name: GII Quickanchor Plus
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: II
Product Code: JDR
Dated: July 21, 2005
Received: July 22, 2005

Dear Ms. Luciano:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act may from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

Sincerely yours,

Mark N. Melkerson
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

## INDICATIONS FOR USE

510(k) Number (if known): K051989

Device Names: GII Quickanchor Plus

Indications for Use:

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Shoulder: Bankart repair, SLAP lesion repair, acromio-clavicular separation, rotator cuff repair, capsule shift/capsulo-labral reconstruction, biceps tenodesis, deltoid repair.

Ankle: Lateral instability, medial instability, achilles tendon repair/reconstruction, midfoot reconstruction.

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Elbow: Tennis elbow repair, biceps tendon reattachment.

Knee: Extra capsular repairs; Reattachment of: medial collateral ligament, lateral collateral ligament, posterior oblique ligament or joint capsule to tibia and joint capsule closure to anterior proximal tibia; extra capsular reconstruction, ITB tenodesis; patellar ligament and tendon avulsions.

Prescription Use ____√___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ___No___ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

**Division Sign-Off)**
**Division of General, Restorative, and Neurological Devices**